REMARKS

The Office has indicated that claims 68-114 are pending; however, claims 69-71 and 73-75 have been deleted in the amendment filed June 29, 2005 with the Request for Continued Examination. The Office has withdrawn claims 96-107 and 111-113 which are directed to a method. Applicants request rejoinder of the method claims, which depend upon allowed product claims, in accordance with MPEP § 821.04. Claims 68, 72, 76-80, 83-96 and 113-115 are now pending. Claim 68 has been amended for clarity. Claim 114 has been amended, support for which is found in claims 80 and 83. Support for new claim 115 is found in claims 77. Claims 69-71 and 73-75 have been previously canceled, thus mooting the rejection as to these claims. Claims 81, 82 and 97-112 have been cancelled without prejudice or disclaimer.

The Invention

The invention is directed to granules comprising microorganisms that allow a higher yield of a compound to be extracted from the granules. The granules contain extruded microorganisms and have a porosity generated by drying of the extruded microorganisms. The granules formed due to such extrusion and drying produce advantageously higher yields of a compound upon extraction. Such a property is thought to be due to the granules' structure that can maximize the access of solvent to be used for the extraction. Please see the application on page 4, lines 22-26. None of the cited references teach or suggest granules having such properties or processes to make such granules. Claim 114 as amended is directed to a granules that also comprise extruded microorganisms and have porosity generated by drying, but particularly comprise arachidonic acid, and have an average dry matter content of 80% or more. The cited references to not suggest that it is desirable to form granules that are extruded and dried such that a porosity is conferred to the granules.

The object of the primary reference Akimoto is to increase production of bishomo-γ-linolenic acid while suppressing the production of arachidonic acid (please see Akimoto, column 1, lines 26-30). Such result is accomplished by using a critical component of a sesame oil, peanut oil or both in a culture medium, which is not required in the present claims. Barclay's object relates to

a food product containing HUFAs. *Mortierella* is specifically disclosed in Barclay as not being a good candidate for producing HUFAs. Huang discloses particular drying processes having the object to retain shape and texture for eating and cooking a food product. Huang does not disclose *Mortierella* as claimed.

Written Description

Applicants traverse the rejection of claims 68-95 and 114 under 35 U.S.C. § 112, first paragraph (written description). The rejection of claims 81 and 82 has been mooted by the cancellation of these claims. The Office objects to the size of the granules as containing new matter. Support for granules having the size diameter as claimed is found in the present application on page 19, lines 15-16. The Examiner points to a preferred embodiment where the fungal biomass "*can be* wholly biomass particles which have a diameter from 0.3 to 10 mm" (emphasis added). Thus, because the fungal biomass "can be" a certain diameter, that does not preclude the granules having other diameters disclosed in the present application. This limitation has been removed from claim 114, thus mooting the rejection as to this claim. Thus, withdrawal of this rejection is respectfully requested.

Obviousness

Applicants traverse the rejection of claims 68-95 and 114 under 35 U.S.C. § 103(a) as being unpatentable over Akimoto (U.S. Patent No. 4,916,066) taken with Barclay (U.S. Patent No. 5,656,319) and Huang (U.S. Patent No. 4,056,638). The Akimoto reference appears to be the U.S. counterpart of the EP Akimoto reference that was cited previously. Similarly, the Barclay reference is a divisional application based on the same parent application as the previously cited Barclay reference, and thus contains the same disclosure. Although these references are applied differently than prior Office actions, many of the issues remain the same.

1. No Motivation to Combine the References

The Court of Appeals for the Federal Circuit has stated that there are three possible sources for a motivation to combine documents: the nature of the problem to be solved, a suggestion

found in the teachings of the prior art, and the notorious nature of one or both of the documents, such that anyone of skill in the art to which the invention pertains would be aware of it or them. *In re Rouffet,* 47 USPQ.2d 1453 (Fed. Cir. 1998). None of these apply here.

The Office alleges that Akimoto teaches a "dry *Mortierella* composition in, *e.g.*, column 8, lines 7-12." Akimoto discloses a method of producing a particular fatty acid (bishomo-γ-linolenic acid) by using a particular culture medium. It is in this particular culture medium that *Mortierella* cells are washed and later dried and which cells are further subjected to hydrolysis, methyl-esterification, and extraction. There is no motivation in this reference to do anything with the dried cells other than subject them to hydrolysis, methyl-esterification, and extraction. In the Akimoto process no granules are formed (but rather some sort of dried cake). Efficient extraction techniques such as percolation extraction wherein the solvent is passed over the granules, which can be effected using the claimed material, cannot be used with Akimoto's composition. Akimoto does not disclose the concept of forming granules, let alone the advantages thereof.

The Examiner appears to have combined Akimoto's dried cells with Barclay's disclosure of wet cells (please see Barclay, column 11, lines 65-67) to arrive at a teaching of *Mortierella* cells which are extruded. However, there is no motivation in Akimoto to use dried *Mortierella* cells in Barclay's process, nor is there motivation in Barclay to use Akimoto's dried cells in Barclay's process. In fact, the reason why Barclay mixes wet cells with grain is to reduce the moisture in the cells. If Akimoto's dried cells were used and were combined with dry ground grain, it is unlikely that such a mixture could be extrudable. Thus, Barclay teaches away from using dry cells in their process which mixes wet cells with dry ground grain such that it is extrudable.

The Office alleges that Barclay "recognizes the advantages of an extruded product regarding reduction of drying time and costs as well as an increase in the bioavailability of the fatty acids upon extrusion." Assuming *arguendo* that the Office intended here to provide motivation to subject Akimoto's wet cells to extrusion, such motivation is misplaced. Barclay teaches extrusion of a mixture of the "cell paste/grain mixture," that is, extrusion to make animal feed, not extrusion of cells or a biomass in general. Furthermore, if Akimoto's wet cells were intended to be selected for combination with Barclay, the Office has not provided motivation to select a particular form of

Akimoto's cells such as cells in the culture broth before culturing or after culturing, cells which have been removed from the broth, or washed cells. Neither reference leads to such a selection because the nature of the problem to be solved in each reference differs. As such, the combination is based on selecting components of each invention based on impermissible hindsight.

Further, Barclay teaches away from using *Mortierella* cells because Barclay is interested in commercially practicable levels of omega-3 highly unsaturated fatty acids and Barclay discloses in column 3, lines 43-45 that *Mortierella* cells are poor candidates for commercial production of omega-3 highly unsaturated fatty acids. Thus, in order to combine Akimoto's *Mortierella* cells with Barclay's disclosure, the object of Barclay will be destroyed, which is impermissible in accordance with MPEP § 2143.01. Again, if the object of an invention is destroyed, there is no motivation to combine the references and no expectation that such a combination would be successful.

Further, the Office relies on Huang. The nature of the problem to be solved by Huang involves making a product that has a substantial protein content and is useful as food. Please see Huang, column 1, lines 47-49. Such a product may closely resemble the texture of meat. Please see Huang, column 1, lines 33-35. The nature of the problem to be solved by Huang is unrelated to the problem to be solved by the present invention (enhancing the extractability of granules), and is also unrelated to the problems to be solved by Akimoto (increasing the production bishomo-γ-linolenic acid) or Barclay (making a food product with a high concentration of HUFAs). Thus, the nature of the problem to be solved does not provide the requisite motivation to combine.

Further, the Office alleges that Huang teaches that *Aspergillus*[1]-containing granules can be subsequently dried. However, assuming there was motivation to combine Akimoto's dry *Mortierella* cells with Barclay's extrusion composition, both the dry *Mortierella* cells and the dry grain would be already dry, so there would be no motivation to further dry the composition. Further, as mentioned above, the dry composition would likely not be extrudable, and thus there would be no granules to dry. Assuming *arguendo* that there is motivation in Barclay to extrude Akimoto's wet cells, which there is not, there is no motivation to further combine Huang's drying step. Huang (column 3, lines 19-51) describes particular drying conditions that are necessary to

retain the texture, shape and integrity of a food product. Huang does not provide motivation to dry a composition to confer porosity.

Thus, applicants find nothing in any document which suggests its combination with any other; the nature of the problem to be solved is not the same in the three references; and none of the references are particularly notorious. Thus, there is no motivation provided for combining these teachings.

2. All of the Claim Elements are not Disclosed

Even if the references were properly combined, the claimed composition does not result. The Office concludes that the "extruded material would reasonably be expected to be porous as claimed, to have the degree of dryness required and to have the dimensions as claim designated." However, the Examiner has not provided any reasoning why there would be such an expectation. As described above, the Office has merely picked certain features from each reference in order to arrive at the claimed invention. Thus, there is no expectation that a combination would have the properties as claimed, and the Office has not provided any reasoning why such properties would be expected.

Moreover, as the porosity, degree of dryness, and dimensions are not disclosed in the cited references, it appears as if the Office has relied on inherency to arrive at these claim elements. However, "the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." Please see MPEP § 2112, IV. The Office has not established that these properties are necessarily present in any of the cited references' compositions, but merely alleges that the material "would reasonably be expected to" have such properties presumably based on a combination of conditions disclosed in the cited references. "The mere fact that a certain thing may result from a given set of circumstances is not sufficient." MPEP § 2112, IV (citations omitted). As inherency may not be relied upon to arrive at the porosity, degree of dryness, and dimensions as claimed, the Office has not established that all of the elements of the claimed invention are found in the cited references as required by MPEP § 2143.

[1] It is noted that Huang does not teach *Aspergillus*.

With regard to the "oil content and sizing," as the Examiner describes in the last paragraph on page 3 of the action, it is not clear what result would occur if the oil content and sizing was varied. The Office has suggested that the composition may be adjusted for optimization purposes, but has not identified which parameters can be varied to obtain which recognized result, as required by MPEP § 2144.05(I)(B). Clarification is respectfully requested.

Further, applicants have previously argued that the art has not taught or suggested all of the claimed limitations. For example, the Office still has not established that the references teach or suggest using a dead microorganism, nor has established the size of the granules (or which result would be obtained if the size was optimized). The Office has also not established the dry matter content defined in claims 83-85 (or which result would be obtained if such a parameter was optimized), nor the porosity of the granules as specifically defined in claims 91-94 (or which result would be obtained if this parameter was optimized). Thus, the Office has not established *prima facie* obviousness because all of the references have not taught or suggested all of the claimed limitations.

3. No Reasonable Expectation of Success

The Office has not established the third prong necessary to establish *prima facie* obviousness in accordance with MPEP § 2143, namely the cited references do not provide a reasonable expectation that the combination would be successful. The invention is directed to dried granules that allow a higher yield of a compound to be extracted from the granules. Such granules that have such property are extruded and have porosity generated by drying as claimed. Please see page 4, lines 22-24; page 6, line 37 to page 7, line 1; page 20, lines 31-36; and Example 25 particularly page 44, line 26-30. None of the cited references recognize this benefit of enhanced extractability. Barclay only recognizes extrusion with respect to preparing animal feed, *e.g.*, extruding a mixture of a cell paste and grain. In a separate context, Barclay discusses extraction, but does not disclose extraction of an extruded product. In fact, Barclay teaches away from extraction of an extruded product. For instance, Barclay in column 13, lines 5-15 discloses extraction of HUFAs and then teaches the *subsequent* addition to food, as in column 3, lines 41-43. There is no recognition of the benefits of extrusion and drying of granules prior to extraction.

Similarly, Akimoto provides no expectation that a composition having enhanced extractability would result upon combining Akimoto's extraction process with Barclay's extrusion process used to make animal feed.

For these reasons, the Office has not established *prima facie* obviousness and withdrawal of this rejection is respectfully requested.

4. Unexpected Results Not Considered

The claimed composition and granules are in a form such that a higher yield than expected of the compound to be isolated can be achieved as described above in Section 3.

In addition, the granules allow efficient extraction techniques to be used such that they can be applied on an industrial scale, such as percolation extraction. Please see, for example, page 6, lines 27-30; page 7, lines 4-6; page 22, lines 22-34; and Examples 16 and 25 of the present specification. Also, comparative Example 8 show that filtered cake of *Mortierella* fermentation broth which was not extruded had a difficult extraction process in comparison to Example 7, which used extruded material. Please see page 27, line 31-32 and page 28, line 6 of the present specification.

In addition, the drying process is facilitated, for example, due to the uniform particle size obtained by the extrusion process. Examples 13, 14 and comparative Example 15 compare drying of the conventional and extruded biomass of *Mortierella alpina* that shows that the extruded biomass had substantially improved drying performance. Please see page 7, lines 2-4; page 32, lines 34-35 through page 33, line 5 of the present specification.

The extrudate not only enables easy drying, but also mild drying conditions, which minimize deterioration of the compound to be extracted, which is a particular advantage for heat- and/or oxidation-sensitive compounds such as PUFA's. Please see, for example, page 8, lines 1-8 of the present specification. None of the references described the unexpected properties of the composition as claimed that provide improved extractability, efficient extraction, improved drying,

and decreased deterioration. Thus, even if, for the sake of argument, *prima facie* obviousness was established, the unexpected results of the claimed composition must be considered.

In the prior response filed June 29, 2005, applicants requested a telephonic interview with the Examiner and the Examiner's supervisor. Applicants respectfully request that such a telephonic interview be granted at the Examiner's convenience.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 251502006900.

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Respectfully submitted,

By _____

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